

# A Fluoroscopic Evaluation of The Navigational Properties of Male Urinary Catheters with Flexible and Non-Flexible Tips: A Study In Cadaveric Specimens

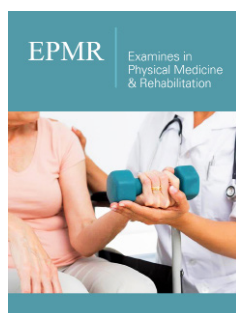
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## Abstract

Intermittent catheterisation is considered as the gold standard for subjects who suffer from urinary retention or incomplete bladder emptying. Essentially two types of male catheter tips are available, a straight tip (Nelaton) and a tapered, curved tip (Coudé or Tiemann). A new omnidirectional, flexible tip has recently been introduced and therefore the navigational properties associated to the various tips of intermittent catheters have been investigated in 9 unselected, fresh, un-embalmed male cadaveric specimens. The hydrophilic catheters were rendered radiopaque through exposure to water soluble contrast media and a <1mm metal piece in the tip. In a randomised fashion the catheters were evaluated with regard to reaching the bladder, ease of insertion and navigational properties. The cadavers (44-88 years old) all displayed some degree of urethral pathology, as expected for this age group. The insertion of catheters with the omnidirectional, flexible tip was in all cases judged as very easy/easy, with no significant difference between them. The fluoroscopic evaluation showed that the omnidirectional properties of the tips were directly translated into smooth less passage of the urethral lumen into the bladder. The conventional catheters did not display such a feature and could in some instances not reach the bladder. The results support the usefulness of flexible catheter tips and future studies in human will disclose whether this mucosal sparing effect has the potential to reduce urethral trauma in subjects in need for intermittent catheterisation.

**Keywords:** Urinary catheters; Fluoroscopy; Cadaver; Flexible catheter tip, Straight tip; Coudé tip; Tiemann tip; Nelaton; SpeediCath® flex

## Introduction

Intermittent catheterisation is considered as the gold standard for subjects who suffer from urinary retention or incomplete bladder emptying [1-3]. Since the introduction of intermittent catheters in the 1970-ties, essentially two types of catheter tips are available, namely those with a straight tip (Nelaton) and those with a tapered, curved tip (Coudé/Tiemann). A variant of the Coudé tip is the rounded distal ball-like olive tip. The catheter tips are believed to be of importance for urethral navigation during catheter insertion, as the tapered Coudé are recommended to ease the prostatic passage [3], whereas tapered olive-shaped tips are believed to assist in negotiation of a urethral stricture [4]. Recently, a new flexible tip has been introduced, in both a straight and a Coudé version, SpeediCath® Flex and SpeediCath® Flex Coudé Pro. The flexibility concerns the neck of the catheter tip, allowing for an omnidirectional bending of up to 90°, a feature that is believed to ease the navigational properties of the catheter in male urethra with irregular anatomy and in this way has the potential to reduce the mechanical traumas to the urethral mucosa during insertion.

The navigational properties associated to the various tips of intermittent catheters have to the best of our knowledge never been shown “live” in video or otherwise visually in humans; fluoroscopy provides a possibility to do so, but as the radiation exposure for such a procedure is considerable [5,6]. it is not a justifiable option in human use. Human cadavers have been

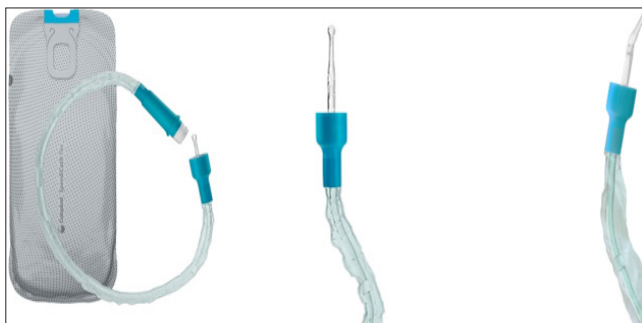
extensively used in studies within urology [7-10]. In the present study, the model was considered the optimal setup for testing catheter insertion since the anatomy is identical to living humans, it is a well-controlled environment that allowed a comparison of catheter insertion and it is possible to document and compare in detail the navigation characteristics of the catheters in the urinary system. As most catheters are invisible on X-rays, a simple method was developed to render the catheters radiopaque.

The objective of the study was to compare the navigational properties of the two new catheters, both with an omnidirectional, flexible tip, but one in a straight (Nelaton) version - SpeediCath Flex® and one in a Coudé version -SpeediCath® Flex Coudé Pro; further to perform a comparison to other catheters with respect to clarify the validity of the cadaveric procedure and to better understand the properties of the flexible tip.

**Materials & Method**

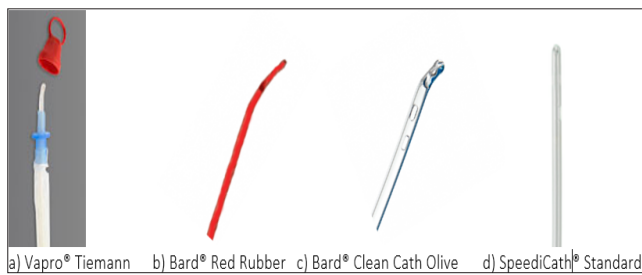
**Catheters investigated and the preparation to render them radiopaque**

**SpeediCath catheters with flexible tips:** SpeediCath® Flex is a straight (Nelaton) catheter whereas SpeediCath® Flex Coudé Pro is a Coudé catheter, with an angulation of 15° just before the omnidirectional, flexible tip (Figure 1). Both are ready to use, hydrophilic male catheters, with the Coudé version being marketed in the United States only.



**Figure 1:** SpeediCath® Flex and SpeediCath® Flex Coudé Pro

**Other catheters investigated**



**Figure 2:** Vapro Tiemann®, Red Rubber®, Clean Cath Olive and SpeediCath® Standard

Figure 2 depicts the three Coudé/ Tiemann and one straight (Nelaton) catheters; Vapro Tiemann® (Coudé), Hollister, a ready-to-use hydrophilic catheter with a 10° angled tip. Red Rubber®, Bard, uncoated with a 32° angled tip and the most flexible of all catheters. Clean Cath Olive®, Bard, a ready-to-use hydrophilic PVC catheter with a 16° angled olive tip. SpeediCath® Standard, a Nelaton ready-to-use hydrophilic catheter.

**Radiopaque catheters**

All catheters investigated in this study were CH12/ 12 French. For preparation, catheters with sleeves had them removed and the hydrophilic catheter dried for 24h. A < 1\*1\*1mm metal piece was inserted into all tips of the catheters to ease fluoroscopic identification. A hydrophilic coating is characterized by the ability to absorb water (swelling media) to render the catheter surface smooth for frictionless insertion with minimal mucosal damage [11]. As injectable non-ionic, iodinated radiographic contrast medium is water soluble, it was hypothesized that it would be absorbed by the hydrophilic coating and thereby make the catheters radiopaque; this was then examined in the dried hydrophilic catheters (SpeediCath Flex®, SpeediCath Flex Coudé Pro®, Coloplast; Vapro Coudé®, Hollister; Bard; Clean Cath Olive®, Bard) which were embedded in contrast medium (Isovue®-300, 300mg/ml, Bracco Diagnostics) for 15, 30, 45 and 60 minutes; the tests demonstrated that absorption period should be ≥ 45 minutes to create the most visible catheters (Figure 3). The red rubber catheter, which is uncoated, was lubricated with a gel prior to use.



**Figure 3:** Catheters embedded in contrast medium for ≥ 45 minutes demonstrates the radiopaque coating and some drops of contrast medium in the lumen of the catheter together with a < 1\*1\*1mm piece of metal in the tips covered by the authors hand to demonstrate radiographic visibility.

At study site, on the day of examination, all catheters were marked at the connector according to randomisation order and subsequently embedded ( $\geq 45$  minutes) in the iodine contrast media.

## Cadavers

Nine fresh and un-embalmed male cadavers were provided as torso's, with information of age, body mass index and cause of death. No other information was available and hence cadavers were unselected and the anatomy of their urethra's unknown. Based on previous experience, it is expected that a fresh cadaver can be catheterized repeatedly up to 6 times without inducing unacceptable changes to the urethra (MK, personal experience). As the essential target of the study was a comparison between the straight SpeediCath® Flex and the SpeediCath® Coudé Pro catheters, these catheters were investigated in all cadavers, whereas the comparison with other tapered catheter types was done in a limited number of cadavers. It was assumed that the risk for urethral perforation would increase with number of insertions of each specimen. The order of catheter insertion was hence randomised in the nine cadaveric specimens.

## Fluoroscopy and catheterisations

Carolinas Surgical Skills Center at Carolinas Medical Center-Mercy is a cadaveric laboratory providing the possibility to examine medical devices, in case urinary catheters, under fluoroscopic control. A retrograde urethrography, blinded to the urologist (MK), visualised the urethra and the bladder of each specimen before insertion of the catheters. According to the randomisation list, the catheters were handed to the urologist who inserted and navigated the catheter blinded to the fluoroscopic screen, as to mimic an ordinary clinical situation and the other author (BPJ) followed the insertion of the catheter to determine when the catheter reached the bladder. At that time, the urologist was asked to evaluate "ease of insertion" on a Likert 1-5 scale. All insertions were recorded on fluoroscopic videos and an image analysis of navigation through difficult urethral passages was performed by the authors.

SpeediCath® Flex and SpeediCath® Flex Coudé Pro were inserted in all cadaveric specimens; SpeediCath® Flex Coudé Pro was inserted twice, both with the tip pointing either cranial (one

catheter) or caudal (one catheter) when entering the meatus. Normal, ready to use and unprepared SpeediCath Flex® unprepared, were inserted to verify no insertion differences between prepared and unprepared catheters. The remaining catheters were inserted in three randomly selected cadavers.

## Evaluations, endpoints and statistical procedures

The main objective of the study was to compare the insertional properties of the two new SpeediCath catheters with a flexible tip. For SpeediCath® Flex Coudé Pro, it was assessed whether the position of the angulated tip when entering the urethra (cranial/caudal) was of importance for outcome. The catheters Clean Cath Olive®, Red Rubber®, Vapro Tiemann® and SpeediCath® (straight) were included as to provide a background to further understand the properties of a flexible tip and to assure the validity of the cadaveric approach. If all catheters behaved indistinguishable the validity of the approach would be seriously questioned, because Coudé/ Tiemann catheters are clinically accepted to be superior in tortuous urethras.

The primary endpoint concerned insertion success in terms of whether the catheter reached the bladder or not (Yes/No). The secondary endpoint concerned "ease of insertion" assessed using an ordinal 5-point Likert scale [1 = Very easy; 2 = Easy; 3 = Neither Nor; 4 = Difficult; 5 = Very difficult], which was evaluated by the urologist (MK) after each catheter insertion. The other secondary endpoint concerned navigational mode through difficult/pathological/narrow urethral passages, classified by the urologist in terms of easy or difficult. Insertion success and ease of insertion were summaries by descriptive statistics for each catheter type. To compare ease of insertion on the 5-point Likert scale for SpeediCath® Flex (normal and unprepared) and SpeediCath® Flex Coudé Pro (cranial and caudal) a proportional odds model was used to analysed the endpoint post hoc. The model included cadaver as a random effect, catheter type as a fixed effect and test order as a covariate. The odds ratios between relevant catheter types as well as the corresponding 95% confidence intervals were estimated, and tests of the hypothesis of no difference between catheter types were performed. All statistical analyses were done with SAS version 9.4 (SAS Institute Inc., Cary, NC).

## Result

### Information on cadavers

**Table 1:** Cadaveric specimen (S), age, BMI, cause of death and urethral anatomy.

Demographic Data from Cadaveric Specimen				Findings During Retrograde Fluoroscopy	
Specimen	Age	BMI	Cause of death	Urethral anatomy	Area of visual narrowing (1st/2nd)
S1	44	22	Pancreatic cancer	Normal	Bulbous/Prostatic
S2	58	18	Cell carcinoma	Normal	Bulbous/Prostatic
S3	68	31	Cardiomyopathy	Normal	Bulbous/Membranous (external Sphincter)
S4	81	23	Chronic Obstructive Pulmonary & Coronary Arterial Disease	Normal	Prostate/Bladder neck

S5	75	19	Acute Myeloid Leukaemia	Normal	Membranous (external sphincter)
S6	88	22	Esophageal cancer	Normal	Membranous (external sphincter)
S7	74	20	Malignant neoplasm unspecified	Normal	Membranous (external sphincter)
S8	73	16	Parkinson's disease	Urethral diverticulum	Membranous (external sphincter)

The information provided concerned age, BMI and cause of death (Table 1); urethral characteristics found during catheter insertions of the nine specimens are also presented. The cadavers had a mean age of 69 years and a mean BMI of 21. Cause of death was

cancer (6 cases), cardiovascular disease (2 cases) and Parkinson's (1 case). No genitourinary cause of death was encountered.

The men all displayed some degree of tortuous urethras on their retrograde urethrography.

### SpeediCath® Flex and SpeediCath® Flex Coudé Pro

**Table 2:** SpeediCath® catheters with omnidirectional, flexible tips; number of insertions (N (%)) performed and Ease of Insertions (EoI) evaluated on a Likert scale 1-5, [1 = very easy, 2= easy, 3 neither nor, 4= difficult, 5= very difficult], given as mean and SD.

	Flex	Flex <sub>unprepared</sub>	Coudé Pro <sub>cranial</sub>	Coudé Pro <sub>caudal</sub>
Insertion N	10	7	13	11
Very easy (1) N (%)	5(50)	3(43)	4(31)	4(36)
Easy (2) N (%)	4(40)	2(29)	6(46)	5(46)
Neither nor (3) N (%)	1(10)	1(14)	0	1(9)
Difficult (4) N (%)	0	0	3(23)	1(9)
Very difficult (5) N (%)	0	1(14)	0	0
Ease of Insertion (EoI) Mean (SD)*	1.6 (0.7)	2.3 (1.5)	2.0 (1.0)	2.0 (1.0)

\*As a catheter type might have been tested more than once on the same cadaver, the Mean and SD was based on the average score per cadaver and catheter type.

Due to the randomization procedures the various catheters were inserted to the same proportion in each cadaver. In total, 24 catheterisations were performed with SpeediCath® Flex Coudé Pro, 13 with the tip at meatal insertion pointing cranial and 11 caudal. Ten insertions were done with SpeediCath® Flex (Flex) and 7 with SpeediCath® Flex unprepared (Flex unprepared), Table 2. In all cases the bladder was reached. The ease of insertion is shown in Table 2, with no significant difference between catheters ( $p=0.43$ ), tip position ( $p=0.48$ ) or radiopaque and unprepared catheter

( $p=0.09$ ).

The navigational properties of the four catheter types are summarised in Table 3 with no difference between them. During the fluoroscopic examination, the flexible tip appeared to smoothly follow the lumen of the bending and narrowing urethra without tendency to be stuck in the urethral wall. In summary, the SpeediCath® catheters with an omnidirectional, flexible tip perform equally well when navigating through the male urethra.

**Table 3:** Navigational properties of the catheters with a flexible tip.

Specimen (S), Location	Flex	Flex unprepared	Coudé Pro <sub>cranial</sub>	Coudé Pro <sub>caudal</sub>
S1 Bulbous	Easy	No video	Difficult	Easy
S1 Prostate	Easy	No video	Easy	Easy
S2 Bulbous	Easy	Easy	Easy	Difficult
S2 Prostate	Easy	Easy	Easy	Easy
S3 Bulbous	Easy	Easy	Easy	Easy
S3 Membranous	Easy	Easy	Easy	Easy
S4 Prostate	Easy	Easy	Easy	Easy
S4 Bladder neck	Easy	Easy	Easy	Easy
S5 Membranous	Not inserted	Not inserted	Easy	Easy

S6 External sphincter	Difficult	No video	Easy	Easy
S7 External sphincter	Easy	Easy	Easy	Easy
S8 Urethral diverticulum	Easy	Not inserted	Easy	Easy
S8 External Sphincter	Easy	Not inserted	Easy	Easy
S9 External Sphincter	Easy	Not inserted	Easy	Easy

**Navigational performances of other catheters**

Due to the randomisation procedure, catheter insertion was equally distributed between the cadaveric specimens. Table 4 provides an overview of the results, and the data from SpeediCath® Flex Coudé Procranial are given as background for comparison.

The bladder was reached with all SpeediCath® Flex Coudé Pro insertions; ease of insertion varied between very ease and easy.

For the Vapro® Tiemann and Clean Cath® catheters, the bladder was reached in 3 out of 4 and 2 out of 5 attempts, respectively, and insertion was easy. In 1 of 4 attempts Red Rubber® reached the bladder with difficulty, and the straight SpeediCath® reached the bladder with some difficulty in 2 of 4 attempts. In Cadaver S5 and S7 all 5 catheters have been tested. In S5 insertion was easy except in red Rubber® and SpeediCath®, whereas in S7 only the SpeediCath® Flex Coudè Pro reached the bladder.

**Table 4:** Bladder insertion (BI) evaluated as Yes/No (Y/N); Ease of Insertion (Eol) evaluated on a Likert scale 1-5, [1 = very easy, 2= easy, 3 neither nor, 4= difficult, 5= very difficult]and navigational properties Easy/Difficult (E/D) of four different Tiemann catheters as well as one straight catheter (SpeediCath®).

Cadaver	SpeediCath®Flex Coudé Pro		Vapro®Tiemann		Clean Cath®		Red Rubber®		SpeediCath®	
	BI	Eol	BI	Eol	BI	Eol	BI	Eol	BI	Eol
S2	Y	2 E	Y	missing						
S3	y	1 E			N	NA				
S3	y	1 E			N	NA				
S5	Y	2 E	Y	3 E	Y	2 E	Y	5 D	Y	5 D
S5			Y	2 E	Y	2 E	N	NA		
S7	Y	2 E	N	NA	N	NA	N	NA	N	NA
S7	Y	2 E								
S8	Y	1 E							Y	3 E
S9	Y	1.6 E					N	NA	N	NA

NA: Not Applicable.

**Discussion**

This study in fresh cadavers indicates that there is no difference with respect to urethral navigation between a straight or Coudé shaped intermittent catheter, SpeediCath® Flex and SpeediCath® Flex Coudé Pro, both equipped with an omnidirectional, flexible catheter tip. Such flexible catheter tips appear to possess the ability to navigate throughout various tortuous anatomies, whereas other “non-flexible” tip Coudé/ Tiemann catheters do not seem to possess this ability, but rather “pushes themselves through the area. Due to the high radiation exposure during continuous fluoroscopy and repeated urethral catheterizations, a human cadaveric model was chosen for the study. Use of cadavers for urologic investigations or training purposes is not unusual [8,10], and the insertional procedure was by the urologist experienced as not being not so different from normal conditions. As the cadaveric procedure was similar for all catheters examined, any differences between

catheters would likely derive from the catheters themselves. If it is possible directly to extrapolate the navigational properties from cadavers to humans is unknown, but it has been shown that such an approach is feasible [7]. The cadaveric finding is also supported by the fact that the omnidirectional, flexible tip navigated efficiently in 75 Tiemann users and so supports the data from this study [12].

Retrograde urethrograms noted tortuous urethral anatomy with noted membranous/prostatic urethral narrowing in the specimens that were not unexpected considering the age of the 9 men. The prevalence of BPH is known to rise markedly with increased age. Autopsy studies have observed a histological prevalence of 8%, 50%, and 80% in the 4th, 6th, and 9th decades of life, respectively [13,14]. For this study it was advantageous, because the potential benefits of a flexible tip would be assumed to be detected easier under such conditions.

Other, similar human studies of intermittent catheter properties visualised through fluoroscopy or other image displaying procedures have to the best of our knowledge not been published. In general, evaluation of intermittent urinary catheter properties is essentially based upon subjective patient assessments of pain and discomfort [11], or of an assessment of hematuria. The present set-up includes a possibility of visual assessment and validation. To omit bias from the urologist performing the catheterisations, he was unable to see the fluoroscopic monitor and so performed the catheterisation blindly as he does in normal practice. Blinding with respect to the individual catheters was inherently not possible and it can hence not be excluded to have played a role.

Our study demonstrates that there is no detectable difference with respect to urethral navigation between the straight (SpeediCath® Flex) or Coudé shaped (SpeediCath® Flex Coudé Pro) intermittent catheter, both with an omnidirectional, flexible catheter tip. This is presumably due to the inherent properties of a flexible tip to be able for “follow” a tortuous, urethral lumen. The non-fixed omnidirectional tip distal to the 15-degree Coudé angle was able to navigate a tortuous bend despite the incorrect caudal position of the Coudé tip. Due to the tip’s omnidirectional flexibility, the Coudé portion of the catheter was able to self-correct its position (turn cranially) to allow ease of insertion. Having a flexible tip may prevent urethral trauma from an inappropriate directional insertion of a fixed Coudé tip catheter.

Navigational data from other intermittent catheters were collected for several reasons. If ease of insertion would have been similar for all catheters, irrespective of being a straight or a Coudé catheter, serious doubts would come up whether a cadaveric model is valid, because it is well accepted that Coudé catheters are superior to straight to insert in narrow and tortuous male urethras [3]. This was however not the case and so the model apparently can detect differences. It seems that the two traditional Coudé/Tiemann catheters (Vapro® Tiemann and Clean Cath®) are not so easy to navigate compared with the catheters with the flexible tip; the straight catheter (SpeediCath®) performed clearly less well in tortuous urethras, as expected. The data from the uncoated Red Rubber® catheter are difficult to interpret because the catheters were just lubricated and did not possess the properties of a hydrophilic coating.

## Conclusion

The data indicate that a flexible catheter tip may ease urethral insertion, irrespective of the catheter type, that is an angulated SpeediCath® Flex Coudé Pro or straight SpeediCath® Flex. The advantage of an omnidirectional, flexible tip also seems to present when compared to other Coudé/Tiemann or straight catheters.

## Conflict of Interest

Michael Kennelly is part of the Coloplast Neuro-urology Advisory Board.

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